

Complete Summary

GUIDELINE TITLE

Schizophrenia: core interventions in the treatment and management of schizophrenia in primary and secondary care.

BIBLIOGRAPHIC SOURCE(S)

National Collaborating Centre for Mental Health. Schizophrenia: core interventions in the treatment and management of schizophrenia in primary and secondary care. London (UK): National Institute for Clinical Excellence (NICE); 2002. 243 p. [262 references]

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

SCOPE
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SCOPE

DISEASE/CONDITION(S)

Schizophrenia

GUIDELINE CATEGORY

Evaluation
 Management
 Treatment

CLINICAL SPECIALTY

Family Practice
Internal Medicine
Psychiatry
Psychology

INTENDED USERS

Advanced Practice Nurses
Allied Health Personnel
Emergency Medical Technicians/Paramedics
Hospitals
Nurses
Occupational Therapists
Patients
Physicians
Psychologists/Non-physician Behavioral Health Clinicians
Social Workers

GUIDELINE OBJECTIVE(S)

To advise on the treatment and management of schizophrenia

Specifically the guideline aims to:

- Evaluate the role of specific pharmacological agents in the treatment and management of schizophrenia
- Evaluate the role of specific psychological interventions in the treatment and management of schizophrenia
- Evaluate the role of specific service delivery systems and service-level interventions in the management of schizophrenia
- Incorporate guidance generated by the National Institutes of Clinical Excellence (NICE) Technology Appraisal Committee on the atypical antipsychotics
- Integrate the above to provide best practice advice on the care of adults with a diagnosis of schizophrenia through the different phases of illness, including the initiation of treatment, the treatment of acute episodes, and the promotion of recovery
- Consider the cost-effectiveness of treatment and service options for people with schizophrenia

TARGET POPULATION

Adults (≥ 18 years) with a diagnosis of schizophrenia (onset < 60 years, without significant physical, sensory, or learning difficulties) and their families/carers

Note: The guidance does not address either very-early onset (childhood-onset schizophrenia) or very-late onset schizophrenia (age of onset at 60 years of age or greater). In addition, this guideline will not provide specific guidance on the management of schizophrenia for people with co-existing learning difficulties, substance misuse, significant physical or sensory difficulties, or those who are homeless.

INTERVENTIONS AND PRACTICES CONSIDERED

Assessment

1. Assessment of service users and carers at the earliest possible opportunity, including medical, social, psychological, occupational, economic, physical, and cultural evaluation of service user
2. Determination of comorbid conditions, including substance and alcohol misuse or physical illness, or the existence of a forensic history

General Management

1. Attainment of informed consent
2. Provision of information and mutual support to service users and carers
3. Use of advance directives
4. Support for seeking a second opinion
5. Early intervention and treatment for first episodes
6. Monitoring the physical health of service users by primary care workers including physical health checks with particular attention to:
 - Development of endocrine disorders (e.g., diabetes, hyperprolactinaemia)
 - Cardiovascular risk factors (blood pressure and lipid levels)
 - Other side effects of medications
 - Lifestyle factors (smoking)
7. Criteria for referral to mental health services
8. Management of treatment-resistant schizophrenia (TRS)

Service-level Interventions

1. Crisis resolution and home treatment teams
2. Early intervention service (EIS)
3. Community mental health teams (CMHTs)
4. Acute day hospitals
5. Assertive outreach teams (or assertive community treatment)
6. Vocational rehabilitation
7. Non-acute day hospital care

Pharmacological Interventions

1. Conventional antipsychotic agents (chlorpromazine and chlorpromazine equivalents, haloperidol)
2. Atypical antipsychotic agents (amisulpride, olanzapine, quetiapine, risperidone, zotepine, clozapine)
3. Other agents, including benzodiazepines (e.g., lorazepam), flumazenil, and anticholinergic agents

Agents mentioned but not recommended: benperidol, flupenthixol, fluphenazine hydrochloride, loxapine, oxypertine, pericyazine, perphenazine, pimozide, promazine hydrochloride, sertindole, sulpiride, thioridazine, trifluoperazine, zuclopenthixol dihydrochloride, lithium, carbamazepine, sodium valproate, lamotrigine, antidepressants, anticonvulsants

Psychological Treatments

1. Cognitive behavioural therapy (CBT)
2. Family interventions

Treatments discussed but not recommended: cognitive remediation, counseling and supportive psychotherapy, psychodynamic psychotherapy and psychoanalysis, psychoeducation, social skills training

Rapid Tranquillisation

1. Identification and minimisation of environmental and social factors that might increase the likelihood of violence and aggression
2. Management of potential and actual violence using de-escalation techniques, restraint, seclusion
3. Use of oral, intravenous, or intramuscular drug administration for rapid tranquillisation
4. Availability of resuscitation equipment
5. Patient debriefing following rapid tranquillisation

MAJOR OUTCOMES CONSIDERED

- Clinical response (including degree of symptomatic recovery, increase in quality of life, degree of personal autonomy, degree and quality of social integration, degree of financial independence)
- Side effects of medications
- Non-adherence with treatment
- Level of risk to self and others
- Morbidity and mortality
- Relapse rate

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

A stepwise, hierarchical approach was taken to locating and presenting evidence to the Guideline Development Group (GDG). This process was developed by the National Collaborating Center for Mental Health (NCCMH) review team after considering recommendations from several sources. These included:

- National Guidelines Support and Research Unit (National Institute for Clinical Excellence [NICE])
- Centre for Clinical Policy and Practice of the New South Wales Health Department (Australia)
- Clinical Evidence Online
- Cochrane Collaboration

- New Zealand Guideline Group
- National Health Service (NHS) Centre for Reviews and Dissemination
- Oxford Centre for Evidence-Based Medicine
- Scottish Intercollegiate Guidelines Network (SIGN)
- United States Agency for Health Research and Quality

The initial evidence base was formed from high-quality, recently published or updated randomised controlled trials (RCTs) that addressed at least one of the clinical questions developed by the GDG. Systematic reviews were selected on predetermined quality criteria. Further searches for new RCTs were undertaken. New RCTs that met inclusion criteria set by the GDG were incorporated into existing systematic reviews and fresh analyses performed. If no systematic reviews were available, the review team located all relevant high quality RCTs for review and, where appropriate, meta-analysis.

Given the size of the evidence base for the treatment and management of schizophrenia, the GDG elected to limit the collection and analysis of data to systematic reviews and RCTs. Although there are a number of difficulties with the use of RCTs in the evaluation of interventions in mental health, some of which also apply to the use of RCTs in any health research, the RCT remains the most important method for establishing efficacy. However, in some cases it was not possible to identify high-quality systematic reviews or a substantial body of RCTs that directly addressed a clinical question. In this situation, an informal consensus process was adopted. Future guidelines on the treatment and management of schizophrenia will be able to update and extend the usable evidence base starting from the evidence collected, synthesized, and analysed for this guideline.

Search Strategies

In conducting the review, the team systematically searched the literature for all English-language systematic reviews relevant to the schizophrenia scope that were published or updated after 1995. (See Appendix 8 of the full version of the original guideline document for a detailed description of the review process.)

Search filters consisted of a combination of subject heading and free-text phrases. The filter for schizophrenia was adapted from that suggested by the Cochrane Schizophrenia Group (May 2001). (The search filters can be found in Appendix 9 of the full version of the original guideline document.)

Electronic searches were made of the major bibliographic databases (MEDLINE, EMBASE, PsycINFO, CINAHL), in addition to the Cochrane Database of Systematic Reviews, the National Health Service Research and Development (NHS R&D) Health Technology Assessment database, Evidence-Based Mental Health, Medical Matrix, and Clinical Evidence (Issue 5).

Ineligible articles were excluded, and a second independent reviewer crosschecked these for relevance. The remaining references were acquired in full and re-evaluated for eligibility. The most recently published reviews that appropriately addressed a clinical question were selected. For each systematic review used, a search was made for new randomized controlled trials (RCTs), and the papers for these and for existing RCTs were retrieved.

The search for further evidence included RCTs published after each review's search date, in-press papers identified by experts, and reviews of reference lists and recent contents of selected papers. All reports that were retrieved but later excluded are listed with reasons for exclusion in the appropriate evidence table. Where no relevant systematic reviews were located, the review team asked the GDG to decide whether a fresh systematic review should be undertaken. Eligible reviews were critically appraised for methodological quality and the reliability of this procedure was confirmed by parallel independent assessment. The eligibility/quality assessment was tested on a representative sample of papers. The GDG checked this process and made adjustments to the guideline review's focus or eligibility criteria as necessary. (Appendix 10 of the full version of the original guideline document provides the eligibility checklist.)

Cost Analysis

Bibliographic electronic databases and health economic databases were searched for economic evidence. The search strategy for economic evidence was based on the schizophrenia spectrum disorders search filter, developed for the clinical literature search, and an economic search filter used by the Centre for the Economics of Mental Health, Institute of Psychiatry, London (Appendix 12 of the full version of the original guideline document lists the search strategy). Search for further evidence included papers from reference lists of eligible studies and relevant reviews. Experts in the field of eating disorders and mental health economics were also contacted to identify additional relevant published and unpublished studies. Studies included in the clinical evidence review and stakeholders' submissions were also screened for economic evidence.

There was no restriction placed on language or publication status of the papers, but only studies published after 1985 were identified by the search strategy. This restriction was deemed appropriate on account of the continuous methodological development in health economics and the greater risk of bias in earlier studies. An exception was made if a study published before 1985 was included in the clinical literature review and contained economic evidence.

The details of the electronic search (interfaces, dates) are reported in Appendix 13 of the full version of the original guideline document.

Upon completion of the database searches, titles and abstracts of all references were screened for relevance to the scope of the guideline. The health economist then assessed relevant papers against the standard inclusion criteria (see Appendix 14 of the full version of the original guideline document) and a modified version of the Drummond et al. checklist (Appendix 15, 16 of the full version of the original guideline document).

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Evidence Categories

I a: Evidence obtained from a single large randomised trial or a meta-analysis of at least three randomised controlled trials

I b: Evidence obtained from a small randomised controlled trial or a meta-analysis of less than three randomised controlled trials

II a: Evidence obtained from at least one well-designed controlled study without randomisation

II b: Evidence obtained from at least one other well-designed quasi-experimental study

III: Evidence obtained from well-designed non-experimental descriptive studies, such as comparative studies, correlation studies, and case studies

IV: Evidence obtained from expert committee reports or opinions and/or clinical experience of respected authorities.

Note: Evidence was classified as 1a if it came from a single trial with at least 150 participants in any single arm of the trial or from 3 or more randomised trials. Evidence was classified as 1b if it came from a single trial with fewer than 150 participants in any single arm of the trial or from less than 3 trials. For the purpose of generating statements, level 1a evidence was regarded as "strong evidence" and level 1b evidence was regarded as "limited evidence."

METHODS USED TO ANALYZE THE EVIDENCE

Meta-Analysis

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Synthesising the Evidence

Outcome data were extracted directly from all eligible randomized controlled trials (RCTs) that met accepted quality criteria into Review Manager 4.1 (Cochrane Collaboration, 2000). Where appropriate, data from the existing trials were synthesised with that from new trials using meta-analytic techniques in Metaview 4.1 (Build 0600; Update Software, 1999). Where necessary, reanalyses of the data or sensitivity analyses were used to answer clinical questions not addressed in the original review.

General information about each eligible systematic review and the included/excluded trials were entered into an evidence table (Appendix 20 of the

full version of the original guideline document lists the evidence tables). Consultation was used to overcome difficulties with coding.

Data from trials included in existing systematic reviews were extracted independently by one reviewer directly into Review Manager and cross-checked with the existing data set. Two independent reviewers extracted data from new RCTs, and disagreements were resolved with discussion. Where consensus could not be reached, a third reviewer resolved the disagreement. Masked assessment (i.e., blind to the journal from which the article comes, the authors, the institution, and the magnitude of the effect) was not used since it is unclear that doing so reduces bias.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus
Informal Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The Guideline Development Group (GDG)

The Schizophrenia GDG consisted of: professionals in psychiatry, nursing, pharmacy, and general practice; academic experts in psychiatry and psychology; a service user; a former service user, and a carer. The guideline development process was supported by staff from the National Collaborating Centre for Mental Health (NCCMH), who undertook the clinical and health economics literature searches, reviewed and presented the evidence to the GDG, managed the process, and contributed to the drafting of the guideline.

Guideline Development Group Meetings

Twenty-three Schizophrenia GDG meetings were held between April 2001 and November 2002. During each day-long GDG meeting, in a plenary session, clinical questions and clinical evidence were reviewed and assessed, statements developed, and recommendations formulated. At each meeting, all GDG members declared any potential conflict of interests, and service user and carer concerns were routinely discussed as part of a standing agenda.

Forming the Recommendations

The GDG was presented with the available research evidence that was relevant to its clinical questions. The systematic reviewer presented evidence tables on each clinical question to the GDG with the results displayed graphically in forest plots. The guideline development group reviewed and analysed the evidence tables and forest plots, which formed the basis for developing statements and recommendations. Recommendations were graded A to C based on the level of associated evidence or noted as a good practice point.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Recommendation Grades

Grade A - At least one randomised controlled trial as part of a body of literature of overall good quality and consistency addressing the specific recommendation (evidence levels Ia and Ib) without extrapolation

Grade B - Well-conducted clinical studies but no randomised clinical trials on the topic of recommendation (evidence levels IIa, IIb, III); or extrapolated from level I evidence

Grade C - Expert committee reports or opinions and/or clinical experiences of respected authorities. This grading indicates that directly applicable clinical studies of good quality are absent (evidence level IV), or with extrapolation from higher levels of evidence

NICE 2002 - Recommendation drawn from the National Institute for Clinical Excellence (NICE) technology appraisal of the use of the newer (atypical) antipsychotic drugs for schizophrenia

Good practice point (GPP) - Recommended good practice based on the clinical experience of the GDG and arrived at through consensus

COST ANALYSIS

Published economic evidence was systematically reviewed in order to collect cost-of-illness information and to consider the cost-effectiveness of different forms of care alongside their clinical effectiveness when formulating recommendations.

The relevant economic evidence was abstracted and presented in terms of both economic evidence tables and narrative summaries alongside the clinical evidence. Health economics evidence was available for the following areas:

- Oral antipsychotics
- Depot antipsychotics
- Rapid tranquilisation
- Cognitive-behavioural therapy
- Family interventions
- Community mental health teams
- Assertive outreach
- Acute day hospital care
- Vocational rehabilitation
- Crisis resolution and home treatment teams
- Early interventions
- Intensive case management

Since economic literature providing information on cost and/or cost-effectiveness was available for most interventions within the scope of the guideline, no further economic analysis including modelling was undertaken.

METHOD OF GUIDELINE VALIDATION

External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

This guideline has been validated through two consultation exercises. The first consultation draft was submitted to the National Institute of Clinical Excellence (NICE) Guidelines Advisory Committee Panel, and circulated to stakeholders and other reviewers nominated by Guideline Development Group (GDG) members.

After taking into account comments from stakeholders, the NICE Guidelines Advisory Committee, a number of health authority and trust representatives, and a wide range of national and international experts from this round of consultation, the GDG responded to all comments and prepared a final consultation draft which was submitted to NICE, circulated to all stakeholders for final comments and posted on the NICE website for public consultation. The final draft was then submitted to the NICE Guidelines Advisory Committee for review prior to publication.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Levels of evidence (I-IV) and grading of recommendations (A-C, GPP) are defined at the end of the Major Recommendations field.

The designation NICE-2002 indicates that the recommendation is from the National Institute for Clinical Excellence (NICE) technology appraisal of atypical antipsychotic drugs.

For the purposes of this guideline, the treatment and management of schizophrenia has been divided into three phases:

- Initiation of treatment at the first episode
- Acute phase
- Promoting recovery

The guideline makes good practice points and recommendations for psychological, pharmacological and service-level interventions in the three phases of care in a service-user and carer-focused integrated mental health service for both primary and secondary care.

Care Across All Phases

Optimism

The effects of schizophrenia on a person's life experience and opportunities are considerable; service users and carers need help and support to deal with their future and to cope with the changes the illness brings.

GPP - Health professionals should work in partnership with service users and carers, offering help, treatment and care in an atmosphere of hope and optimism.

Getting Help Early

For most people experiencing a schizophrenic breakdown, the level of distress, anxiety, and subjective confusion, especially during first episodes, leads to difficulty in accessing services.

GPP - Service users and their relatives seeking help should be assessed and receive treatment at the earliest possible opportunity.

Assessment

The purpose of this guideline is to help improve the experience and outcomes of care for people with schizophrenia. These outcomes include the degree of symptomatic recovery, quality of life, degree of personal autonomy, ability and access to work, stability and quality of living accommodation, degree and quality of social integration, degree of financial independence, and the experience and impact of side effects.

GPP - The assessment of needs for health and social care for people with schizophrenia should, therefore, be comprehensive and address medical, social, psychological, occupational, economic, physical, and cultural issues.

Working in Partnership with Service Users and Carers

GPP - Health professionals involved in the routine treatment and management of schizophrenia should take time to build a supportive and empathic relationship with service users and carers; this should be regarded as an essential element of the routine care offered.

The families of people with schizophrenia often play an essential part in the treatment and care of their relative and, with the right support and help, can positively contribute to promoting recovery. Parents of people with schizophrenia often feel to blame, either because they have "passed on" the genes causing schizophrenia, or because they are "bad parents."

GPP - Clear and intelligible information should be made available to service users and their families about schizophrenia and its possible causes, and about the possible role families can have in promoting recovery and reducing relapse.

Consent

Whatever treatments are offered, it is essential to engage the service user in a collaborative, trusting and caring, working relationship at the earliest opportunity. Professionals should take into full account the particular nature of schizophrenia: namely, that the illness may affect people's ability to make judgments, to recognise that they are ill, to comprehend clearly what professionals might say to them, and to make informed decisions about their treatment and care.

GPP - Health professionals should make all efforts necessary to ensure that a service user can give meaningful and properly informed consent before treatment is initiated, giving adequate time for discussion, and the provision of written information.

Providing Good Information and Mutual Support

GPP - Health professionals should provide accessible information about schizophrenia and its treatment to service users and carers; this should be considered an essential part of the routine treatment and management of schizophrenia.

GPP - In addition to the provision of good-quality information, families and carers should be offered the opportunity to participate in family or carer support programmes, where these exist.

Language and Culture

GPP - When talking to service users and carers, health professionals should avoid using clinical language or keep it to a minimum. Where clinical language is used, service users and carers should have access to written explanations.

GPP - All services should provide written material in the language of the service user, and interpreters should be sought for people who have difficulty in speaking English.

Advance Directives

NICE 2002 - Although there are limitations with advance directives regarding the choice of treatment for individuals with schizophrenia, it is recommended that they are developed and documented in individuals' care programmes whenever possible.

GPP - When advance directives have been agreed, copies should be placed in primary-care and secondary-care case notes/care plans, and copies given to the service user and his or her care coordinator. If appropriate, and subject to agreement with the service user, a copy should be given to his or her carer.

Initiation of Treatment (First Episode)

Early Referral

It is most likely that the first point of contact for people who may be developing schizophrenia for the first time will be a primary care professional. Rapid identification, early referral, and good liaison with secondary services are a priority.

GPP - In primary care, all people with suspected or newly diagnosed schizophrenia should be referred urgently to secondary mental health services for assessment and development of a care plan. If there is a presumed diagnosis of

schizophrenia, then part of the urgent assessment should include an early assessment by a consultant psychiatrist.

Early Intervention Services

GPP - Because many people with actual or possible schizophrenia have difficulty in getting help, treatment, and care at an early stage, it is recommended that early intervention services are developed to provide the correct mix of specialist pharmacological, psychological, social, occupational, and educational interventions at the earliest opportunity.

GPP - Where the needs of the service user and/or carer exceed the capacity of early intervention services, referral to crisis resolution and home treatment teams, acute day hospitals, or inpatient services should be considered.

Early Treatment

GPP - Where there are acute symptoms of schizophrenia, the general practitioner (GP) should consider starting atypical antipsychotic drugs at the earliest opportunity--before the individual is seen by a psychiatrist, if necessary. Wherever possible, this should be following discussion with a psychiatrist, and referral should be a matter of urgency.

Pharmacological Intervention

NICE 2002 - It is recommended that the oral atypical antipsychotic drugs amisulpride, olanzapine, quetiapine, risperidone, and zotepine are considered in the choice of first-line treatments for individuals with newly diagnosed schizophrenia.

C - Atypical antipsychotics at the lower end of the standard dose range are the preferred treatments for a person experiencing a first episode of schizophrenia.

Second Opinion

After the first episode, many people are unsure about their diagnosis and may need help with this.

GPP - A decision by the service user, and carer where appropriate, to seek a second opinion on the diagnosis should be supported, particularly in view of the considerable personal and social consequences of being diagnosed with schizophrenia.

Treatment of the Acute Episode

Service-level Interventions

The services most likely to help people who are acutely ill include crisis resolution and home treatment teams, early intervention teams, community mental health teams (CMHTs), and acute day hospitals. If these services are unable to meet the needs of a service user, or if the Mental Health Act is used, inpatient treatment

may prove necessary for a period of time. Whatever services are available, a broad range of social, group, and physical activities are essential elements of the services provided.

C - Community mental health teams are an acceptable way of organising community care and may have the potential for effectively coordinating and integrating other community-based teams providing services for people with schizophrenia. However, there is insufficient evidence of their advantages to support a recommendation which precludes or inhibits the development of alternative service configurations.

B - Crisis resolution and home treatment teams should be used as a means to manage crises for service users and as a means of delivering high-quality acute care. In this context, teams should pay particular attention to risk monitoring as a high-priority routine activity.

C - Crisis resolution and home treatment teams should be considered for people with schizophrenia who are in crisis to augment the services provided by early intervention services and assertive outreach teams.

C - Crisis resolution and home treatment teams should be considered for people with schizophrenia who may benefit from early discharge from hospital following a period of inpatient care.

A - Acute day hospitals should be considered as a clinical and cost-effective option for the provision of acute care, both as an alternative to acute admission to inpatient care and to facilitate early discharge from inpatient care.

GPP - Social, group, and physical activities are an important aspect of comprehensive service provision for people with schizophrenia as the acute phase recedes, and afterwards. All care plans should record the arrangements for social, group, and physical activities.

Pharmacological Interventions

During an acute episode, antipsychotic drugs are necessary. Wherever possible, service users should make an informed choice as to the antipsychotic they prefer. If a service user is unable to make his or her preference known, an atypical should be prescribed. It is best to use a single drug, using doses within the British National Formulary (BNF) dose range and not to use high or loading doses. Clinical response and side effects should be monitored routinely and regularly. If, with conventional antipsychotics, side effects are troublesome or symptom control is inadequate, an atypical should be offered. During an acute episode, some service users become behaviourally disturbed and may need rapid tranquillisation. The recommendations for this can be found in the section below titled "Rapid Tranquillisation".

NICE 2002 - The choice of antipsychotic drug should be made jointly by the individual and the clinician responsible for treatment based on an informed discussion of the relative benefits of the drugs and their side-effect profiles. The individual's advocate or carer should be consulted where appropriate.

NICE 2002 - Antipsychotic therapy should be initiated as part of a comprehensive package of care that addresses the individual's clinical, emotional, and social needs. The clinician responsible for treatment and key worker should monitor both therapeutic progress and tolerability of the drug on an ongoing basis. Monitoring is particularly important when individuals have just changed from one antipsychotic to another.

C - The dosage of conventional antipsychotic medication for an acute episode should be in the range of 300-1000 mg chlorpromazine equivalents per day for a minimum of 6 weeks. Reasons for dosage outside this range should be justified and documented. The minimum effective dose should be used.

C - In the treatment of the acute episode for people with schizophrenia, massive loading doses of antipsychotic medication, referred to as "rapid neuroleptization," should not be used.

NICE 2002 - The oral atypical antipsychotic drugs (amisulpride, olanzapine, quetiapine, risperidone, zotepine) should be considered as treatment options for individuals currently receiving conventional antipsychotic drugs who, despite adequate symptom control, are experiencing unacceptable side effects, and for those in relapse who have previously experienced unsatisfactory management or unacceptable side effects with conventional antipsychotic drugs. The decision as to what are unacceptable side effects should be taken following discussion between the patient and the clinician responsible for treatment.

NICE 2002 - When full discussion between the clinician responsible for treatment and the individual concerned is not possible, in particular in the management of an acute schizophrenic episode, the oral atypical drugs should be considered as the treatment options of choice because of the lower potential risk of extrapyramidal symptoms (EPS). In these circumstances, the individual's carer or advocate should be consulted where possible and appropriate. Although there are limitations with advance directives regarding the choice of treatment for individuals with schizophrenia, it is recommended that they are developed and documented in individuals' care programmes whenever possible.

NICE 2002 - It is not recommended that, in routine clinical practice, individuals change to one of the oral atypical antipsychotic drugs if they are currently achieving good control of their condition without unacceptable side effects with conventional antipsychotic drugs.

C - Antipsychotic drugs, atypical or conventional, should not be prescribed concurrently, except for short periods to cover changeover.

B - When prescribed chlorpromazine, individuals should be warned of a potential photosensitive skin response as this is an easily preventable side effect.

B - Where a potential to cause weight gain or diabetes has been identified (and/or included in the Summary of Product Characteristics) for the atypical antipsychotic being prescribed, there should be routine monitoring in respect of these potential risks.

Early Post-acute Period

Towards the end of an acute episode of schizophrenia, service users should be offered help to better understand the period of illness, and given the opportunity to write their account in their notes. Carers may also need help in understanding the experience. Assessment for further help to minimise disability, reduce risk, and improve quality of life should be routinely undertaken during recovery from the acute phase. In particular, psychological and family help, contingency planning, and identifying local resources/services are important. Advice about drug treatments to maintain recovery is also important.

Service User Focus

GPP - Consideration should be given, where practicable, to encouraging service users to write their account of their illness in their notes.

GPP - Psychoanalytic and psychodynamic principles may be considered to help health professionals to understand the experience of individual service users and their interpersonal relationships.

Assessment

The purpose of this guideline is to help improve the experience and outcomes of care for people with schizophrenia. These outcomes include the degree of symptomatic recovery, quality of life, degree of personal autonomy, ability and access to work, stability and quality of living accommodation, degree and quality of social integration, degree of financial independence, and the experience and impact of side effects.

GPP - The assessment of needs for health and social care for people with schizophrenia should, therefore, be comprehensive and address medical, social, psychological, occupational, economic, physical, and cultural issues.

Psychological Treatments

A - Cognitive behavioural therapy (CBT) should be available as a treatment option for people with schizophrenia.

A - Family interventions should be available to the families of people with schizophrenia who are living with or who are in close contact with the service user.

C - Counselling and supportive psychotherapy are not recommended as discrete interventions in the routine care of people with schizophrenia where other psychological interventions of proven efficacy are indicated and available. However, service user preferences should be taken into account, especially if other more efficacious psychological treatments are not locally available.

Medication Advice

GPP - Given the high risk of relapse following an acute episode, the continuation of antipsychotic drugs for up to 1 to 2 years after a relapse should be discussed with service users, and carers where appropriate.

GPP - Withdrawal from antipsychotic medication should be undertaken gradually whilst regularly monitoring signs and symptoms for evidence of potential relapse.

GPP - Following withdrawal from antipsychotic medication, monitoring for signs and symptoms of potential relapse should continue for at least 2 years after the last acute episode.

Promoting Recovery

There are a number of options for promoting and maintaining recovery. The general principles for all phases apply equally in this situation. Early intervention to provide early additional treatment and care should the need arise remains important.

Primary Care

Primary care professionals have an important part to play in the physical and mental health care of people with schizophrenia. They are best placed to monitor the physical health of people with schizophrenia and should do so regularly. Case registers will be an important means of doing so. In addition, primary care workers should monitor the mental health and treatment of their service users, work closely with secondary services, and refer before crises arise wherever possible.

GPP - The organisation and development of practice case registers for people with schizophrenia is recommended as an essential step in monitoring the physical and mental health of people with schizophrenia in primary care.

GPP - GPs and other primary health workers should regularly monitor the physical health of people with schizophrenia registered with their practice. The frequency of checks will be a clinical decision made jointly between the service user and clinician. The agreed frequency should be recorded in the patient's notes.

GPP - Physical health checks should pay particular attention to endocrine disorders, such as diabetes and hyperprolactinaemia, cardiovascular risk factors, such as blood pressure and lipids, side effects of medication, and lifestyle factors such as smoking. These must be recorded in the notes.

GPP - The decision to re-refer a service user from primary care to mental health services is a complex clinical judgment that should take account of the views of the service user and, where appropriate, carers. Issues of confidentiality should be respected when involving carers. Referral may be considered in a number of circumstances, but particular factors indicating referral include the following:

- Where treatment adherence is a problem, referral is usually indicated.
- A poor response to treatment would make referral a higher priority.
- If comorbid substance misuse is suspected, referral is indicated.

- If the level of risk to self or others is increased, referral to secondary services is indicated.
- When a person with schizophrenia first joins a GP practice list, referral to secondary services for assessment and care programming is indicated, subject to the full agreement of the service user.

Secondary Services

Secondary services should undertake regular and full assessment of the mental and physical health of their service users, addressing all the issues relevant to a person's quality of life and well-being. When a service user chooses not to receive physical care from his or her GP, this should be monitored by doctors in secondary care. Carers should be contacted routinely, subject to the agreement of the service user, and should be provided with a care plan.

The possible presence of comorbid conditions, including substance and alcohol misuse or physical illness, or the existence of a forensic history, will necessitate the development of treatment and care plans outside the scope of this guideline. Nevertheless, full assessment of these issues should be included.

GPP - A full assessment of health and social care needs should be undertaken regularly, including assessment of accommodation and quality of life, the frequency of which should be based upon clinical need, and following discussion with the service user. The agreed frequency of assessment should be documented in the care plan.

The higher physical morbidity and mortality of service users with schizophrenia should be considered in all assessments. Whilst this would normally be expected to be the role of primary care services, secondary care services should nevertheless monitor these matters where they believe a service user may have little regular contact with primary care.

GPP - Primary and secondary care services, in conjunction with the service user, should jointly identify which service will take responsibility for assessing and monitoring the physical health care needs of service users. This should be documented in both primary and secondary care notes/care plans and clearly recorded by care coordinators for those on the enhanced care programme approach (CPA).

GPP - Moreover, all non-professional carers who provide regular care for a person on CPA should have an assessment of their caring, physical and mental health needs, at a frequency agreed in conjunction with the carer and recorded in their own (carer) care plan.

Service Interventions

The range of services needed for people with schizophrenia are diverse and need to be tailored to individual circumstances and current local resources. However, some people with schizophrenia have high needs for care and tend to be lost from ordinary services. Assertive outreach teams (or assertive community treatment [ACT]) are an effective way of helping to meet those needs and are better at

staying in touch than ordinary services. Also, most people with schizophrenia will need rapid access to help in crises. Services need to plan how to best deliver help and treatment ensuring that teams are functionally integrated.

B - Assertive outreach teams should be provided for people with serious mental disorders including people with schizophrenia.

B - Assertive outreach teams should be provided for people with serious mental disorders, including for people with schizophrenia, who make high use of inpatient services and who have a history of poor engagement with services leading to frequent relapse and/or social breakdown (as manifest by homelessness or seriously inadequate accommodation).

B - Assertive outreach teams should be provided for people with schizophrenia who are homeless.

GPP - Where the needs of the service user and/or carer exceed the capacity of assertive outreach teams, referral to crisis resolution and home treatment teams, acute day hospitals, or inpatient services should be considered.

C - Crisis resolution and home treatment teams should be considered for people with schizophrenia who are in crisis to augment the services provided by early intervention services and assertive outreach teams.

GPP - Integrating the care of people with schizophrenia who receive services from community mental health teams, assertive outreach teams, early intervention services and crisis resolution, and home treatment teams should be carefully considered. The CPA should be the main mechanism by which the care of individuals across services is properly managed and integrated.

Psychological Interventions

Psychological treatments should be an indispensable part of the treatment options available for service users and their families in the effort to promote recovery. Those with the best evidence of effectiveness are cognitive behavioural therapy and family interventions. These should be used to prevent relapse, to reduce symptoms, increase insight, and promote adherence to medication.

Relapse Prevention and Symptom Reduction: Cognitive Behavioural Therapy and Family Interventions

A - Cognitive behavioural therapy should be available as a treatment option for people with schizophrenia.

A - In particular, cognitive behavioural therapy should be offered to people with schizophrenia who are experiencing persisting psychotic symptoms.

B - Cognitive behavioural therapy should be considered as a treatment option to assist in the development of insight.

C - Cognitive behavioural therapy may be considered as a treatment option in the management of poor treatment adherence.

B - Longer treatments with cognitive behavioural therapy are significantly more effective than shorter ones, which may improve depressive symptoms but are unlikely to improve psychotic symptoms. An adequate course of cognitive behavioural therapy to generate improvements in psychotic symptoms in these circumstances should be of more than 6 months' duration and include more than ten planned sessions.

A - Family interventions should be available to the families of people with schizophrenia who are living with or who are in close contact with the service user.

A - In particular, family interventions should be offered to the families of people with schizophrenia who have recently relapsed or who are considered at risk of relapse.

A - Also in particular, family interventions should be offered to the families of people with schizophrenia who have persisting symptoms.

B - When providing family interventions, the length of the family intervention programme should normally be longer than 6 months' duration and include more than ten sessions of treatment.

B - When providing family interventions, the service user should normally be included in the sessions, as doing so significantly improves the outcome. Sometimes, however, this is not practicable.

A - When providing family interventions, service users and their carers may prefer single-family interventions rather than multi-family group interventions.

Pharmacological Interventions

Antipsychotic drugs are an indispensable treatment option for most people in the recovery phase of schizophrenia. The main aim here is to prevent relapse and help keep a person stable enough to live as normal a life as possible. Drugs are also necessary for psychological treatments to be effective.

The service user and clinician should jointly decide the choice of drug, but service user preferences are central. Oral and depot preparations can be used. Follow British National Formulary (BNF) guidance on dosing and test dosing. If conventional antipsychotics have been used and are not effective or are causing unacceptable side effects, change to an atypical. If an atypical is causing diabetes or excessive weight gain, this must be monitored or consider changing to a different atypical or a conventional antipsychotic. Always monitor and record clinical response, side effects, and service user satisfaction. If a person is satisfied with the drug he or she is taking, make no changes. Do consider the use of psychological interventions if a person has persisting symptoms or frequent relapses.

If a service user has had two antipsychotics (including one atypical) each for 6-8 weeks without significant improvement, check out possible causes for a lack of response and consider clozapine. In some circumstances it may be supportable to add a second antipsychotic drug to clozapine if there has been a suboptimal response at standard doses. Do not use more than one antipsychotic drug in other situations, except when changing from one drug to another. Other adjunctive treatments are outside the scope of this guideline.

Relapse Prevention: Oral Antipsychotics

NICE 2002 - The choice of antipsychotic drug should be made jointly by the individual and the clinician responsible for treatment based on an informed discussion of the relative benefits of the drugs and their side-effect profiles. The individual's advocate or carer should be consulted where appropriate.

NICE 2002 - The oral atypical antipsychotic drugs (amisulpride, olanzapine, quetiapine, risperidone and zotepine) should be considered as treatment options for individuals currently receiving typical antipsychotic drugs who, despite adequate symptom control, are experiencing unacceptable side effects, and for those in relapse who have previously experienced unsatisfactory management or unacceptable side effects with typical antipsychotic drugs. The decision as to what are unacceptable side effects should be taken following discussion between the patient and the clinician responsible for treatment.

NICE 2002 - It is not recommended that, in routine clinical practice, individuals change to one of the oral atypical antipsychotic drugs if they are currently achieving good control of their condition without unacceptable side effects with typical antipsychotic drugs.

NICE 2002 - Antipsychotic therapy should be initiated as part of a comprehensive package of care that addresses the individual's clinical, emotional, and social needs. The clinician responsible for treatment and key worker should monitor both therapeutic progress and tolerability of the drug on an ongoing basis. Monitoring is particularly important when individuals have just changed from one antipsychotic to another.

C - Targeted, intermittent dosage maintenance strategies should not be used routinely in lieu of continuous dosage regimens because of the increased risk of symptom worsening or relapse. However, these strategies may be considered for service users who refuse maintenance or for whom some other contraindication to maintenance therapy exists, such as side-effect sensitivity.

C - Antipsychotic drugs, atypical or conventional, should not be prescribed concurrently, except for short periods to cover changeover.

Relapse Prevention: Depot Antipsychotics

NICE 2002 - A risk assessment should be performed by the clinician responsible for treatment and the multidisciplinary team regarding concordance with medication, and depot preparations should be prescribed when appropriate.

B - Depot preparations should be a treatment option where a service user expresses a preference for such treatment because of its convenience or as part of a treatment plan in which the avoidance of covert non-adherence with antipsychotic drugs is a clinical priority.

A - For optimum effectiveness in preventing relapse, depot preparations should be prescribed within the standard recommended dosage and interval range.

GPP - Following full discussion between the responsible clinician and the service user, the decision to initiate depot antipsychotic injections should take into account the preferences and attitudes of the service user towards the mode of administration and organisational procedures (for example, home visits and location of clinics) related to the delivery of regular intramuscular injections.

GPP - Test doses should normally be used as set out in the BNF and full licensed prescribing information on depot antipsychotics is available from the summary of product characteristics, which can be found in the electronic medicines compendium (www.emc.vhn.net).

GPP - As with oral antipsychotics, people receiving depots should be maintained under regular clinical review, particularly in relation to the risks and benefits of the drug regimen.

Treatment-resistant Schizophrenia

GPP - The first step in the clinical management of treatment-resistant schizophrenia (TRS) is to establish that antipsychotic drugs have been adequately tried in terms of dosage, duration, and adherence. Other causes of non-response should be considered in the clinical assessment, such as comorbid substance misuse, poor treatment adherence, the concurrent use of other prescribed medicines, and physical illness.

C - If the symptoms of schizophrenia are unresponsive to conventional antipsychotics, the prescribing clinician and service user may wish to consider an atypical antipsychotic in advance of a diagnosis of treatment-resistant schizophrenia and a trial of clozapine. In such cases, olanzapine or risperidone may be worth considering. Service users should be informed that, while these drugs may possibly be beneficial, the evidence for improvement in this situation is more limited than for clozapine.

NICE 2002 - In individuals with evidence of TRS, clozapine should be introduced at the earliest opportunity. TRS is suggested by a lack of satisfactory clinical improvement despite the sequential use of the recommended doses for 6 to 8 weeks of at least two antipsychotics, at least one of which should be an atypical.

Combining Antipsychotics

C - Antipsychotic drugs, atypical or conventional, should not be prescribed concurrently, except for short periods to cover changeover.

C - However, the addition of a second antipsychotic to clozapine may be considered for people with TRS for whom clozapine alone has proved insufficiently effective.

Employment

The overall aim of mental health services is to help service users get back to living an ordinary life as far as possible. Assessment should be comprehensive and this includes assessing a person's work potential. Mental health and social care services also need to help support the development of employment opportunities for people with schizophrenia.

GPP - People with schizophrenia experience considerable difficulty in obtaining employment and many remain unemployed for long periods of time. The assessment of people with schizophrenia should include assessment of their occupational status and potential. This should be recorded in their notes/care plans.

C - Supported employment programmes should be provided for those people with schizophrenia who wish to return to work or gain employment. However, it should not be the only work-related activity offered when individuals are unable to work or are unsuccessful in their attempts to find employment.

GPP - Mental health services, in partnership with social care providers and other local stakeholders, should enable people to use local employment opportunities, including a range of employment schemes to suit the different needs and level of skill, for people with severe mental health problems, including people with schizophrenia.

Rapid Tranquillisation

During an acute illness, some service users can become behaviourally disturbed and may need help to calm down; for the majority of service users, though, rapid tranquillisation is not necessary and should not be resorted to routinely. It is important to ensure that the environment is properly adapted for the needs of the acutely ill and that communication between staff and service users is clear and therapeutic in order to minimise frustration and misunderstandings. Staff on psychiatric inpatient units should be trained in how to assess and manage potential and actual violence using de-escalation techniques, restraint, seclusion, and rapid tranquillisation. Staff should also be trained to undertake cardiopulmonary resuscitation.

If drugs are needed to calm an individual, an oral preparation should be offered first. If intramuscular injection proves necessary, lorazepam, haloperidol, or olanzapine are the preferred drugs. If two drugs are needed, consider lorazepam and haloperidol. If haloperidol is used, anticholinergics should be administered. Vital signs and side effects should be regularly monitored and full physical and mental health assessment undertaken at the earliest opportunity. Rapid tranquillisation may be traumatic--patients will need debriefing with full explanation, discussion, and support.

C - Health professionals should identify and take steps to minimise the environmental and social factors that might increase the likelihood of violence and aggression during an episode, particularly during periods of hospitalisation. Factors to be routinely identified, monitored, and corrected include overcrowding, lack of privacy, lack of activities, long waiting times to see staff, poor communication between patients and staff, and weak clinical leadership.

Aims of Rapid Tranquillisation

The aim of drug treatment in such circumstances is to calm the person and reduce the risk of violence and harm, rather than treat the underlying psychiatric condition. An optimal response would be a reduction in agitation or aggression without sedation, allowing the service user to participate in further assessment and treatment. Ideally, the drug should have a rapid onset of action and a low level of side effects.

C - Staff who use rapid tranquillisation should be trained in the assessment and management of service users specifically in this context: this should include assessing and managing the risks of drugs (benzodiazepines and antipsychotics), using and maintaining the techniques and equipment needed for cardiopulmonary resuscitation, prescribing within therapeutic limits, and using flumazenil (benzodiazepine antagonist).

Training for Behavioural Control/Rapid Tranquillisation

C - Staff need to be trained to anticipate possible violence and to de-escalate the situation at the earliest opportunity, and physical means of restraint or seclusion should be resorted to "only after the failure of attempts to promote full participation in self-care."

C - Training in the use and the dangers of rapid tranquillisation is as essential as training in de-escalation and restraint. Health professionals should be as familiar with the properties of benzodiazepines as they are with those of antipsychotics.

C - Specifically, health professionals should:

- Be able to assess the risks associated with rapid tranquillisation, particularly when the service user is highly aroused and may have been misusing drugs or alcohol, be dehydrated, or possibly be physically ill
- Understand the cardiorespiratory effects of the acute administration of these drugs and the need to titrate dosage to effect
- Recognise the importance of nursing, in the recovery position, people who have received these drugs and also of monitoring pulse, blood pressure, and respiration
- Be familiar with, and trained in, the use of resuscitation equipment; this is essential, as an anaesthetist or experienced "crash team" may not be available
- Undertake annual retraining in resuscitation techniques
- Understand the importance of maintaining an unobstructed airway.

Principles of Rapid Tranquillisation

C - The psychiatrist and the multidisciplinary team should, at the earliest opportunity, undertake a full assessment, including consideration of the medical and psychiatric differential diagnoses.

C - Drugs for rapid tranquillisation, particularly in the context of restraint, should be used with caution because of the following risks:

- Loss of consciousness instead of sedation
- Over-sedation with loss of alertness
- Possible damage to the therapeutic partnership between service user and clinician
- Specific issues in relation to diagnosis

C - Resuscitation equipment and drugs, including flumazenil, must be available and easily accessible where rapid tranquillisation is used.

C - Because of the serious risk to life, service users who are heavily sedated or using illicit drugs or alcohol should not be secluded.

C - If a service user is secluded, the potential complications of rapid tranquillisation should be taken particularly seriously.

C - Violent behaviour can be managed without the prescription of unusually high doses or "drug cocktails." The minimum effective dose should be used. The BNF recommendations for the maximum doses (BNF - section 4.2) should be adhered to unless exceptional circumstances arise.

GPP - With growing awareness that involuntary procedures produce traumatic reactions in service users, following the use of rapid tranquillisation, service users should be offered the opportunity to discuss their experiences and should be provided with a clear explanation of the decision to use urgent sedation. This should be documented in their notes.

GPP - Service users should also be given the opportunity to write their account of their experience of rapid tranquillisation in the notes.

Route of Drug Administration

C - Oral medication should be offered before parenteral medication.

C - If parenteral treatment proves necessary, the intramuscular route is preferred over the intravenous one from a safety point of view. Intravenous administration should only be used in exceptional circumstances.

C - Vital signs must be monitored after parenteral treatment is administered. Blood pressure, pulse, temperature, and respiratory rate should be recorded at regular intervals, agreed by the multidisciplinary team, until the service user becomes active again. If the service user appears to be or is asleep, more intensive monitoring is required.

Pharmacological Agents Used in Rapid Tranquillisation

C - The intramuscular (IM) preparations recommended for use in rapid tranquillisation are lorazepam, haloperidol, and olanzapine. Wherever possible, a single agent is preferred to a combination.

C - When rapid tranquillisation is urgently needed, a combination of IM haloperidol and IM lorazepam should be considered.

C - IM diazepam is not recommended for the pharmacological control of behavioural disturbances in people with schizophrenia.

C - IM chlorpromazine is not recommended for the pharmacological control of behavioural disturbances in people with schizophrenia.

C - When using IM haloperidol (or any other IM conventional antipsychotic) as a means of behavioural control, an anticholinergic agent should be given to reduce the risk of dystonia and other extrapyramidal side effects.

Definitions:

Evidence Categories

I a: Evidence obtained from a single large randomised trial or a meta-analysis of at least three randomised controlled trials

I b: Evidence obtained from a small randomised controlled trial or a meta-analysis of less than three randomised controlled trials

II a: Evidence obtained from at least one well-designed controlled study without randomisation

II b: Evidence obtained from at least one other well-designed quasi-experimental study

III: Evidence obtained from well-designed non-experimental descriptive studies, such as comparative studies, correlation studies, and case studies

IV: Evidence obtained from expert committee reports or opinions and/or clinical experience of respected authorities.

Recommendation Grades

Grade A - At least one randomised controlled trial as part of a body of literature of overall good quality and consistency addressing the specific recommendation (evidence levels Ia and Ib) without extrapolation

Grade B - Well-conducted clinical studies but no randomised clinical trials on the topic of recommendation (evidence levels IIa, IIb, III); or extrapolated from level I evidence

Grade C - Expert committee reports or opinions and/or clinical experiences of respected authorities. This grading indicates that directly applicable clinical studies of good quality are absent (evidence level IV), or with extrapolation from higher levels of evidence

NICE 2002 - Recommendation drawn from the NICE technology appraisal of the use of the newer (atypical) antipsychotic drugs for schizophrenia

Good practice point (GPP) - Recommended good practice based on the clinical experience of the GDG and arrived at through consensus

CLINICAL ALGORITHM(S)

Clinical algorithms are provided for:

- Management of the Acute Episode of Schizophrenia and Management in the Early-Post-Acute Phase
- Promoting Recovery
- Physical Care
- Rapid Tranquillisation in Schizophrenia
- Management of Poor Response to Treatment and Treatment Resistance (After the Acute Phase)
- Pathways to care

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Consistent and improved quality of care and outcomes for people with schizophrenia

POTENTIAL HARMS

- Potential side effects of antipsychotic agents include diabetes, weight gain, extrapyramidal symptoms (parkinsonism, acute dystonic reactions, akathisia and tardive dyskinesia), autonomic effects (such as blurring of vision, increased intra-ocular pressure, dry mouth and eyes, constipation and urinary retention), increased prolactin levels, seizures, sexual dysfunction, lethargy, and quality of life issues. Cardiac safety is also an issue because several antipsychotics have been shown to prolong ventricular repolarisation, which is associated with an increased risk of ventricular arrhythmias.
- Chlorpromazine therapy may result in a potential photosensitive skin response

- Routine monitoring is a pre-requisite of clozapine use because of the risk of neutropenia and agranulocytosis.
- Rapid tranquillisation has a potential risk of cardiovascular and cardiorespiratory events.
- Benzodiazepines may cause cognitive impairment, behavioural disinhibition, over-sedation and, most seriously, respiratory depression with the administration of high doses.
- Flumazenil can induce seizures in people who have been receiving regular benzodiazepines.
- The use of depot medication delivery systems has a lack of flexibility of administration, with adjustment to the optimal dosage being a protracted and uncertain process. Controlled studies of low-dose maintenance treatment with depot preparations suggest that any increased risk of relapse consequent upon a dose reduction may take months or years to become manifest.
- For some people, receiving the depot injection, there have been reports of pain, oedema, pruritis, and sometimes a palpable mass at the injection site.

CONTRAINDICATIONS

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Antipsychotic agent maintenance therapy is contraindicated in patients with side-effect sensitivity.

QUALIFYING STATEMENTS

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- This guidance represents the view of the Institute, which was arrived at after careful consideration of the evidence available. Health professionals are expected to take it fully into account when exercising their clinical judgment. The guidance does not, however, override the individual responsibility of health professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.
- Guidelines are not a substitute for professional knowledge and clinical judgment. Guidelines can be limited in their usefulness and applicability by a number of different factors: the availability of high-quality research evidence, the quality of the methodology used in the development of the guideline, the generalisability of research findings and the uniqueness of individual patients.
- Although the quality of research in schizophrenia is variable, the methodology used here reflects current international understanding on the appropriate practice for guideline development (Appraisal of Guidelines for Research and Evaluation [AGREE] Instrument; www.agreecollaboration.org), ensuring the collection and selection of the best research evidence available, and the systematic generation of treatment recommendations applicable to the majority of service users and situations. However, there will always be some patients and situations for which clinical guideline recommendations are not readily applicable. This guideline does not, therefore, override the individual responsibility of health professionals to make appropriate decisions in the

- circumstances of the individual service user, in consultation with the service user and/or carer.
- In using guidelines, it is important to remember that the absence of empirical evidence for the effectiveness of a particular intervention is not the same as evidence for ineffectiveness. In addition, of particular relevance in mental health, evidence-based treatments are often delivered within the context of an overall treatment programme including a range of activities, the purpose of which may be to help engage the service user, and provide an appropriate context for the delivery of specific interventions. It is important to maintain and enhance the service context in which these interventions are delivered; otherwise the specific benefits of effective interventions will be lost. Indeed, the importance of organising care, so as to support and encourage a good therapeutic relationship, is at times greater than the specific treatments offered.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

General

The implementation of this guideline will build on the National Service Frameworks for Mental Health in England and Wales and should form part of the service development plans for each local health community in England and Wales. The Priorities and Planning Framework for the National Health Service (NHS) in England 2003-2006 sets key targets for improvements in mental health services including compliance with relevant NICE technology appraisals and clinical guidelines. Separate mental health strategies in Wales, for adults and for children and adolescents, were published in September 2001.

Local health communities should review their existing service provision for people with schizophrenia against this guideline as they begin the development of their Local Delivery Plans. The review should consider the resources required to implement fully the recommendations set out in Section 1 of the short version of the original guideline and in the "Major Recommendations" section of this summary, the people and processes involved, and the timeline over which full implementation is envisaged. Clearly, it is in the interests of service users and carers that the implementation timeline, as determined by each local health community, is as rapid as possible. NHS organisations should consider the value of advising service users and carers of their response to this guidance. In addition, NHS organisations should review the skills of existing staff and teams, identify gaps and put in place training arrangements that will ensure that staff are adequately equipped to implement the recommendations in this guideline.

Relevant local clinical guidelines and protocols should be reviewed in the light of this guidance and revised accordingly.

Audit

To enable clinicians to audit their own compliance with this guideline it is recommended that, if not already in place, management plans are recorded for

each patient. This information should be incorporated into local clinical audit data recording systems and consideration given (if not already in place) to the establishment of appropriate categories in electronic record systems.

Prospective clinical audit programmes should record the proportion of patients whose treatment and care adheres to the guideline. Such programmes are likely to be more effective in improving patient care when they form part of the organisation's clinical governance arrangements and when they are linked to specific postgraduate activities.

Suggested audit criteria are listed in section 8 of the full version of the guideline and in Appendix E of the short version of the original guideline document. These can be used as the basis for local clinical audit, at the discretion of those in practice.

IMPLEMENTATION TOOLS

Audit Criteria/Indicators
Clinical Algorithm
Patient Resources
Staff Training/Competency Material
Wall Poster

For information about [availability](#), see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

National Collaborating Centre for Mental Health. Schizophrenia: core interventions in the treatment and management of schizophrenia in primary and secondary care. London (UK): National Institute for Clinical Excellence (NICE); 2002. 243 p. [262 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

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GUIDELINE DEVELOPER(S)

National Collaborating Centre for Mental Health - National Government Agency
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GUIDELINE COMMITTEE

Guideline Development Group

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Committee Members: Dr Tim Kendall (Chair), Co-Director, National Collaborating Centre for Mental Health, Deputy Director, Royal College of Psychiatrists Research Unit; and Consultant Psychiatrist and Medical Director, Community Health, Sheffield NHS Trust; Mr Stephen Pilling (Facilitator), Co-Director, National Collaborating Centre for Mental Health, Director, Centre for Outcomes Research and Effectiveness, and Consultant Clinical Psychologist, Camden and Islington Mental Health and Social Care Trust; Professor Tom Barnes (Lead, Topic Group on Pharmacology), Professor of Psychiatry, Imperial College Faculty of Medicine, London; Professor Philippa Garety (Lead, Topic Group on Psychological Interventions), Professor of Clinical Psychology, Guy's King's and St Thomas' School of Medicine and the Institute of Psychiatry, King's College London and the South London and Maudsley NHS Trust; Professor Max Marshall (Lead, Topic Group on Service-level Interventions), Professor of Psychiatry, University of Manchester; Ms Emma Harding, Service User, and Senior Project Worker, User Employment Programme, SW London St George's Mental Health NHS Trust; Mr Graham Estop, Mental Health Charities in NICE; Mr Bill Hare, Rethink Severe Mental Illness; Mr Peter Pratt, Chief Pharmacist, Doncaster & South Humber NHS Trust and Community Health Sheffield NHS Trust; Dr Paul Rowlands, Consultant Psychiatrist, Derbyshire Mental Health Services NHS Trust; Professor Irwin Nazareth, Professor of Primary Care and Population Studies, Royal Free and University College London Medical School; Ms Liz Newstead, Lecturer/Clinical Nurse Specialist, Dorset Healthcare NHS Trust/Bournemouth University; Ms Christine Sealey (Observer), Guidelines Commissioning Manager, NICE

NCCMH Staff: Dr Catherine Pettinari: Senior Project Manager; Dr Craig Whittington: Senior Systematic Reviewer; Dr Judit Simon: Health Economist; Ms Rachel Burbeck: Systematic Reviewer; Mr Daniel Michelson: Research Assistant; Mr Lawrence Howells: Research Assistant; Ms Ellen Boddington: Research Assistant; Ms Celia Morgan: Research Assistant

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

At each Guideline Development Group (GDG) meeting, all GDG members declared any potential conflict of interests.

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format [PDF] format from the [National Institute for Clinical Excellence \(NICE\) Web site](#).

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Schizophrenia: core interventions in the treatment and management of schizophrenia in primary and secondary care. NICE guideline. 2002 Dec. 62 p. Electronic copies: Available in Portable Document Format [PDF] format from the [National Institute for Clinical Excellence \(NICE\) Web site](#).
- Schizophrenia: core interventions in the treatment and management of schizophrenia in primary and secondary care. Clinical practice algorithms and pathways to care. 2002 Dec. 3 p. Available in Portable Document Format [PDF] format from the [National Institute for Clinical Excellence \(NICE\) Web site](#).
- Schizophrenia: core interventions in the treatment and management of schizophrenia in primary and secondary care. Using and understanding the NICE guideline: a training session. 2003 Mar. Available from the [National Institute for Clinical Excellence \(NICE\) Web site](#). This training session is also available on CD-ROM. To order, please call the NHS Response Line on 0870 1555 455 and quote reference number N0203. Alternatively e-mail your request with your name and address to schizophreniatraining@nice.nhs.uk.

Additionally, Audit Criteria can be found in Chapter 8 of the [original guideline document](#).

PATIENT RESOURCES

The following is available:

- Treating and managing schizophrenia (core interventions). Understanding NICE guidance -- information for people with schizophrenia, their advocates and carers, and the public. 2002 Dec. 39 p.

Electronic copies: Available in Portable Document Format [PDF] format from the [National Institute for Clinical Excellence \(NICE\) Web site](#).

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for

them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC STATUS

This NGC summary was completed by ECRI on January 7, 2005. The information was verified by the guideline developer on March 17, 2005.

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